SECTION 5 – 510K Summary

K080209

Fisher&Paykel HEALTHCARE

SEP 12 2008

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Contact person	Tina Mason
Date Prepared	25th January 2008
Trade Name	Zest™ Nasal Mask
Common Name	Nasal Mask
Classification Name	Non continuous ventilator IPPB (21 CFR § 868.5905, product code BZD)
Predicate Devices	K063036 Fisher & Paykel Healthcare Opus HC482 Direct Nasal Mask K061236 Fisher & Paykel Healthcare Flexifit HC432 Full Face Mask (predicate for material biocompatibility)

5.1 Description

The Zest™ Nasal Mask is a respiratory mask which is non invasive, the Silicone Seal is positioned over the nose, and it seals on the area around the nose, and the upper lip. The mask is held on the face with headgear straps. It connects to a single breathing tube via a swivel adaptor, to receive pressurized gases. On the mask base are exhalation vents (bias holes) that allow exhaled gases to be continually flushed and removed to room air. The silicone seal is contoured for comfort and to reduce leakage.

5.2 Intended Use

The Zest™ Nasal Mask is intended for single patient adult use by individuals who have been diagnosed by a physician as requiring CPAP or Bi-level ventilator treatment in the home, hospital or other clinical setting.

5.3 Technological Characteristics Comparison

The Zest™ Nasal Mask is very similar to the predicate Fisher & Paykel Healthcare Opus HC482 Direct Nasal Mask. Both masks are for non continuous ventilation, and deliver CPAP gasses through the nose. The main difference is the way the seal is achieved, the Zest Nasal Mask seals around the nose and on the upper lip, where the Opus HC482 Direct Nasal Mask seals on the entrance of the nostrils. Other differences are that the Zest Nasal Mask has 4 headgear attachment points (as opposed to 2 in the Opus). The Zest Nasal Mask has only one size, where the Opus HC482 has 3 sizes (the Zest Nasal Mask is designed to fit a large proportion on the patient population with only one size) and the Zest Nasal Mask has a larger dead space due the way it achieves a seal on the face.

5.4 Non-clinical Tests

Testing of the Zest™ Nasal Mask was compared to the predicate Fisher & Paykel Healthcare Opus HC482 Direct Nasal Mask for performance and the HC432 Full Face Mask for biocompatibility. These tests demonstrate substantial equivalence of the Zest™ Nasal Mask to the predicate mask. Copies of test reports are included in Appendix B.

5.5 Conclusion

The comparison of features, performance, and intended use demonstrate that the Zest™ Nasal Mask is substantially equivalent to the predicate Fisher & Paykel Healthcare Opus HC482 Direct Nasal Mask for performance and the HC432 Full Face Mask for biocompatibility. The Zest™ Nasal Mask is proven to be safe and effective for CPAP and Bi-level ventilation therapy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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SEP 12 2008

Ms. Tina Mason
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NEW ZEALAND

Re: K080209
Trade/Device Name: Zest™ Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: July 28, 2008
Received: July 30, 2008

Dear Ms. Mason:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

SECTION 4 – Indications for Use Statement

510(k) Number

Device Name Zest™ Nasal Mask

Indications for Use:

The Zest™ Nasal Mask is intended for single patient adult use by individuals who have been diagnosed by a physician as requiring CPAP or Bi-level ventilator treatment in the home, hospital or other clinical setting.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080209